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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/490,965	01/24/2000	Michael J Heller	249/292	7864

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O'MELVENY & MEYERS
114 PACIFICA, SUITE 100
IRVINE, CA 92618

EXAMINER

DEJONG, ERIC S

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 07/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/490,965

Applicant(s)

HELLER ET AL.

Examiner

Eric S. DeJong

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 May 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 83-91, 95, 99-101, 104, 105 and 107 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 91 is/are allowed.
- 6) ☒ Claim(s) 83 and 84 is/are rejected.
- 7) ☒ Claim(s) 85-90, 95, 99-101, 104, 105, and 107 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED OFFICE ACTION

Information Disclosure Statement

The response filed by applicants on 23 May 2005 contained a request for a copy of the PTO Form-1449 submitted on April, 2004, with the Japanese reference (JP 05 285000) initialed by the Examiner. Applicants are notified that a copy of the PTO Form-1449 submitted on April, 2004, with the Japanese reference (JP 05 285000) initialed by the Examiner was mailed to applicants on 01 November 2004. A second copy is **not** included with this office action, though applicants may obtain a second copy through the Patent Application Information Retrieval (PAIR) system as outlined below.

Withdrawal of Claim Rejections - 35 USC § 112

The previous rejection of claims 91, 95, 99-101, 104, 105, and 107 under 35 U.S.C. 112, second paragraph, is withdrawn in view of amendments made to the instant claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 83 and 84 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kreisher (P/N 4,589,965), taken in view of Ramachandran et al. (P/N 5,109, 124). This rejection is reiterated and maintained from the previous office action, mailed 12/16/03.

The instant claims are drawn to a method for electronically controlled enzymatic reaction at an addressable location comprising providing an array of microlocations comprising a permeation layer coupled to a plurality of electrodes, contacting a biomolecule in solution with the permeation layer at a microlocation, contacting the biomolecule at the microlocation, attaching the biomolecule to the permeation layer at the microlocation, and reacting an enzyme with the biomolecule at the microlocation.

Kreisher described the practice of electroblotting which utilizes an electrode on one side of a gel with a membrane/paper and electrode on the other side to transfer proteins, nucleic acids, and other materials to the paper or membrane in column 1, lines 31-57. Oppose charge to whatever material or molecule is being transferred is required for such electroblotting to be operative as is instantly claimed also. This general process binds the transferred molecules to the membrane as described in the bridging sentences between column 1 and 2. The SUMMARY OF THE INVENTION section in column 2-3 describes the invention as improving electroblotting using plate electrodes. Various additional materials which may be electroblotted are described in column 3, lines 28-67. Of specific interest is the generic suggestion and motivation in column 3 lines 28-67, for utilizing a variety of biochemical reaction types including hybridization probes, various labeling methods, double reactions (line 61) to identify probes, and

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substrate/enzyme reactions on the blote (lines 65-67). This column 3 section; as well as column 3, line 68, through column 4, line 4 is reasonably directed to suggesting and motivating the practice of a variety of biochemical reactions on blotted, solid support bound, materials and/or molecules. Kreisher does not specify particular reactions such as where a substrate is bound via electroblotting followed by enzyme reaction as in instant claim 83 or the PCR type amplification as in instant claim 91.

Ramachandran et al describes the detection of a polynucleotide probe via signaling moieties as summarized in the abstract. Such a probe is utilized to hybridize to a target nucleic acid as further described in column 5, lines 38-52. This is exemplified in more detail in examples 3 and 4 in columns 11-14. In column 13, line 1 through column 14, line 51, a hybridization assay is described wherein target DNA is immobilized onto a membrane, hybridized with a probe labeled for detection. The detection of the hybridized probe is performed via the visualization described in example 3 in column 12, lines 15-44, wherein the enzyme, alkaline phosphatase, is reacted via attachment to the probe which is immobilized on the membrane in a conjugate which is then visualized via color reaction. It is noted that the instant claims do not limit what type of reaction which the enzyme performs with the immobilized substrate on the membrane.

Therefore it would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains to perform the electroblotting of Kreisher to immobilize a substrate nucleic acid onto a membrane which is then reacted via binding reactions with an enzyme as in Ramachandran et al.

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to result in the practice of the instant invention to obtain the benefits of color detection via the labels as in Ramachandran et al.

Response to Arguments

Applicants assert that neither Kreisher nor Ramachandran et al. teach or suggest the limitation of an array of microlocations comprising a permeation layer coupled to a plurality of electrodes. Applicants argue that the citation of Kreisher are referring to systems in the prior art and are not alternative embodiments of the disclosed system.

Applicants arguments filed 23 May 2005 have been fully considered but are not found persuasive. Applicants acknowledge that “the electrodes are laid out in a grid fashion” and in a “platinum grid system” as discussed in Kreisher are prior art. Applicants further admit that Kreisher preferred plate electrode system is compared to that of a platinum grid system in Kreisher column 4, lines 62 through column 7, line 10. The position set forth in Kreisher is that the disclosed invention is an improvement upon such previously known and used systems. Thus, Kreisher not only teaches the preferred embodiments of a plate system, but also embodiments wherein “electrodes are laid out in a grid fashion” and a “platinum grid system” thus anticipating the instantly claimed limitations of an array of microlocations comprising a permeation layer coupled to a plurality of electrodes, wherein each microlocation comprises an electrode coupled to the permeation layer”.

As discussed above, Kreisher described the practice of electroblotting which utilizes an electrode on one side of a gel with a membrane/paper and electrode on the

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other side to transfer proteins, nucleic acids, and other materials to the paper or membrane in column 1, lines 31-57. Under a reasonably broad interpretation, the claimed limitation of "providing an array of microlocations comprising a permeation layer coupled to a plurality of electrodes" is anticipated by the teachings of Kreisher. The membrane coupled to two electrodes does provide a surface containing a plurality of microlocations wherein biomolecules are concentrated. For the benefit of applicants, the Examiner suggests that an amendment to claim 1 containing a limitation of an array of microlocations comprising a permeation layer, wherein each microlocation is coupled individually to a distinct electrode on a one to one basis within the plurality of electrodes, would be sufficient in overcoming the prior art rejection on the basis of either Kreisher or Ramachandran et al.

Applicants further assert that neither Kreisher nor Ramachandran et al. teach or suggest the limitations of "contacting a biomolecule in a solution with the permeation layer at a microlocation" and "concentrating the biomolecule at the microlocation by placing the electrode of the microlocation at an opposite charge to the biomolecule. Applicants argue that system disclosed by Kreisher concerns electrophoretically resolved material in a gelatin sheet and is therefore already resolved prior to being placed between electrodes.

Applicants arguments filed 23 May 2005 have been fully considered but are not found persuasive. The instant claims do not contain any limitation that would exclude materials that have already undergone some process of purification or resolving, such

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as the electrophoretically purified material as disclosed in Kresher. Further, the biomolecules are in a buffered solution contained within a gel matrix and, therefore, reasonably seen as existing in a solution state.

Claim Objections

Claims 85-90, 95, 99-101, 104, 105, and 107 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. This objection is maintained from the previous office action.

Allowable Subject Matter

Claim 91 is allowable.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instrument Examiner, Tina Plunkett, whose telephone number is (571) 272-0549.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric S. DeJong whose telephone number is (571) 272-6099. The examiner can normally be reached on 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, Ph.D. can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now

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contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center at (800) 786-9199.

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John S. Brusca 13 July 2005
JOHN S. BRUSCA, PH.D
PRIMARY EXAMINER